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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,773	08/21/2001	Robert E. Reiter	30435.54USD3	9474

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MANDEL & ADRIANO
55 SOUTH LAKE AVENUE
SUITE 710
PASADENA, CA 91101

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/15/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,773

Applicant(s)

REITER ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2003 and 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53,56-62 and 87-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53,56-62 and 87-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 54, 55, and 63-86 have been canceled and claims 53, 56-57, 59-61, 87-88 have been amended and claims 89-99 have been added in the amendment filed 1/21/0.
2. Claims 53, 56-62, 87-99 are under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. The following Office Action contains some NEW GROUNDS of rejection.

Specification

5. The substitute specification has been entered, however, the claims and the abstract were not entered because of duplication.
6. The disclosure is objected to because of the following informalities:
 - a. The specification should be updated to include all SEQ ID Nos for all sequences in the specification. For example that listed on page 70.
 - b. the first line of the specification needs to be updated to indicate application 09/564329 is now US Patent 6,541212 and application 09/359326 is abandoned.Appropriate correction is required.

Rejections Withdrawn

7. The rejection of claims 53-63 and 87-88 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

8. The rejection of Claim 87 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment to the claim.

9. The rejection of claims 53, 56-62 and 87-88 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the successful completion of the deposit requirements.

10. The rejection of claims 53, 56-62, 88 under 35 U.S.C. 112, first paragraph, is withdrawn in view of arguments.

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11. The rejection of Claims 1, 53-60, 87 under 35 U.S.C. 102(e) as being anticipated by Au-Young (U.S. Patent 5,856,136, filed 7/96) is withdrawn in view of arguments.

12. The rejection of claim 53 and 87 under 35 U.S.C. 102(a) as being anticipated by Reiter et al (PNAS 95:1735-40, 2/98) is withdrawn in view of the amendments to the claims.

13. The rejection of claims 53, 56-62 and 87 under 35 U.S.C. 102(a) as being anticipated by Reiter et al (WO 98/40403, published 9/1998) is withdrawn in view of the new grounds of rejection.

14. The rejection of claims 1, 53-63, 87-88 under 35 U.S.C. 103(a) as being unpatentable over Au-young (U.S. Patent 5,856,136, filed 7/96) as applied to claims 1, 53-60, 87 above, and further in view of Vitetta et al (Biologic Therapy of Cancer, J.B. Lippincott Company, page 482-495, 1991) is withdrawn in view of arguments.

15. The rejection of claims 1, 53, 55, 60, 61, 63, 87-88 under 35 U.S.C. 103(a) as being unpatentable over Reiter et al (PNAS 95:1735-1740, 2/98) as applied to claim 1, 53, 55, 87 above, and further in view of Vitetta et al (Biologic Therapy of Cancer, J.B. Lippincott Company, page 482-495, 1991) and Thomas et al (Antibodies Volume II, A practical approach, IRL Press, pages 223-245, 1989) is withdrawn in view of the amendments to the claims .

16. The rejection of claims 1, 53-63, 87-88 under 35 U.S.C. 103(a) as being unpatentable over Reiter et al (WO 98/40403, published 9/98) is withdrawn in view of the new grounds of rejection.

Response to Arguments

Priority

17. Claim 53 recites the limitation of an antibody that competes for binding to the 2A2 antibody. The limitation of the 2A2 and 3G3 antibody is first seen in application 09/203939. Therefore claims 53, 56-62, and 87-88 are granted the priority date of 12/98. Newly added claims 89, 91, 95, and 98 are granted the priority date of 12/98 for the same reasons above because these claims have the 2A2 and/or 3G3 antibodies in them. Claims 90, 92, 93, 94, 96, 97 are granted the priority date of 3/98.

18. The rejection of Claims 53, 56-62, 87-88 and newly added claims 89-99 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 69-86 of copending Application No. 09/359,326 is maintained.

The response filed 1/21/03 has been carefully considered but is deemed not to be persuasive. The response states that applicants will gladly revisit this issue upon allowance (see page 9 of response). In response to this argument, no terminal disclaimer has been filed and as such the rejection is maintained.

19. The rejection of claims 53, 56-62, 87-88 and newly submitted claims 89-99 rejected under the judicially created doctrine of obviousness-type double patenting as

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being unpatentable over claims 1-3 of U.S. Patent No. 6,258,939 and further in view of Vitetta et al (Biologic therapy of Cancer, J.B. Lippincott Company, pages 482-495, 1991) and Queen et al (U.S. Patent 5,693,762, filed 6/95) is maintained.

The response filed 1/21/03 has been carefully considered but is deemed not to be persuasive. The response states that applicants will gladly revisit this issue upon allowance (see page 9 of response). In response to this argument, no terminal disclaimer has been filed and as such the rejection is maintained.

The following are some NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

20. Claims 53, 56-62, 87-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 53, 56-62, 87-99 are indefinite for reciting "monoclonal antibody designated...produced by the hybridoma designated" in claims 53 and 97-98 because the exact meaning of the phrase is not clear. Does the claim mean that the antibody that binds to the epitope is produced by the hybridoma designated in the claim or are antibodies 1G8, etc produced by the hybridomas recited in the claims?

b. Claim 87 is indefinite for reciting "effective amount" because the phrase "an effective amount" is indefinite when the claims fails to state the function which is to be achieve. In re Frederiksen, 213 F 2d 547, 102 USPQ 35 (CCPA 1954).

c. Claim 87 is indefinite for reciting "binds to the extracellular domain of SEQ ID NO:2" because the exact meaning of the phrase is not clear. The specification does not describe an extracellular domain in SEQ ID NO:2, therefore it is unclear what the difference between SEQ ID NO:2 is and an "extracellular domain" of SEQ ID NO:2.

Claim Rejections - 35 USC § 102

21. Claims 53, 56-62, 87, 89, 91, 95, 98 are rejected under 35 U.S.C. 102(a) as being anticipated by Reiter et al (WO 98/40403, published 9/1998) and as evidenced from the specification.

The claims recite a monoclonal antibody that specifically binds an epitope bound by monoclonal antibodies 2A2 and 3G3, further recited is a chimeric, humanized, recombinant, Fab, an immunoconjugate comprising a cytotoxic agent of PE and compositions comprising such. For this rejection the intended use of the composition of claim 87 for use in killing human cells is given no patentable weight.

Reiter et al teach monoclonal, chimeric, and recombinant antigen binding fragments of antibodies to SEQ ID NO:2, PSCA and immunoconjugated comprising the antibody and PE (see page 13). Reiter et al teach the antibodies bind to distinct epitopes and epitope mapping for antibodies recited in claim 53 (see page 13, 35-37) and compositions comprising such. As evidenced from the specification in Figure 49 several of the 1G8, 3C5, 2H9, A410, 3E6 bind the same epitope as 2A2 and 3G3. therefore, because of the priority date of the claims Reiter et al reads on the claims

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because several of the antibodies of Reiter et al bind to the same epitope as 2A2 and 3G3.

The response filed 2/18/03 states that the claims being rejected are entitled to the 3/98 date and as such the Reiter et al publication is not art and Reiter et al is art on the 2A2 and 3G3 antibodies but is not relevant because Reiter et al does not disclose or recite the two antibodies (see page 7 of response). In response to these arguments, the claims are granted the priority date of 12/98 and even though Reiter et al does not teach the 2A2 or 3G3 antibody Reiter et al does teach antibodies that bind to the same epitope as evidenced from Figure 49 of the specification.

22. Claim 99 is rejected under 35 U.S.C. 102(b) as being anticipated by Au-Young (U.S. Patent 5,856,136, filed 7/96).

The claim recites a monoclonal antibody that binds amino acid residues 85-123 of SEQ ID NO:2.

Au-Young teach a protein that is identical to SEQ ID NO:2, PSCA except for one amino acid at position 49, but which is encompassed by SEQ ID NO:2 (see SEQ ID NO:2 of Au-Young). Au-Young teach monoclonal antibodies to SEQ ID NO:2 (see column 13-14). Au-Young teach production of antibodies by determining regions of high immunogenicity and analysis to select epitopes such as those near the C-terminal or in hydrophilic regions as shown in Figure 5. Thus, it would be inherent that antibodies to the C-terminus would be antibodies that bind to a portion of residues 85-123 of SEQ ID NO:2.

Claim Rejections - 35 USC § 103

23. Claims 53, 56-62, 87, 88, 89, 91, 95, 98 are rejected under 35 U.S.C. 103(a) as being anticipated by Reiter et al (WO 98/40403, published 9/1998) and as evidenced from the specification.

Claims 53, 56-62, 87, 89, 91, 95, 98 have been described supra. Claim 88 recites a kit comprising the antibody and a label. For this rejection the intended use of the composition of claim 87 for use in killing human cells is given no patentable weight.

Reiter et al has been described supra. Reiter et al does not exemplify a kit comprising the antibody and a detectable label but this is obvious and common in the art.

Claim 88 recites a kit comprising an antibody and a detectable label. Although the claim recites a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the references read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detectably labeling antibodies also were well known and available to the ordinarily skilled artisan.

Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

24. No claim is allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

26. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.